AMENDMENTS TO THE CLAIMS

1. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:

(a) a controlled release core ~~consisting essentially of metformin or a pharmaceutically acceptable salt thereof and~~ comprising at least one pharmaceutically acceptable excipient and only one active drug that consists of metformin hydrochloride; and

(b) an immediate release thiazolidinedione derivative containing component wherein not less than 85%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0, wherein the thiazolidinedione derivative can be either pioglitazone or a pharmaceutically acceptable salt thereof and after storage at 40°C and 75% relative humidity for three months, the total thiazolidinedione related compounds or impurities in the dosage form is not more than 0.6% as determined by high performance liquid chromatography and each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.25% wherein the thiazolidinedione related compounds and impurities are:

(i) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-5-hydroxy-2,4-thiazolidinedione;

(ii) (z)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzylidene]-2,4-thiazolidinedione;

(iii) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-3-[2-(5-ethyl-2-pyridyl)ethyl]-2,4-thiazolidinedione;

(iv) (+/-)-ethyl-2-carbamoyltio-3-[4-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-] propionate; and

(v) ethyl-3-p-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-propionate.

2. (original) The pharmaceutical dosage form as defined in claim 1 wherein not less than 90%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
3. (original) The pharmaceutical dosage form as defined in claim 1 wherein not less than 95%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
4. (original) The pharmaceutical dosage form as defined in claim 1 wherein not less than 100%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
5. (canceled).
6. (canceled).
7. (canceled).
8. (canceled).
9. (canceled).
10. (canceled).
11. (canceled).
12. (canceled).
13. (canceled).
14. (canceled).
15. (previously presented) The pharmaceutical dosage form as defined in claim 1 wherein the total thiazolidinedione related compounds are not more than 0.5%.
16. (canceled)
17. (previously presented) The pharmaceutical dosage form as defined in claim 15 wherein each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.20%.
18. (original) The pharmaceutical dosage form as defined in claim 17 wherein each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.10%.

19. (original) The dosage form of claim 1 wherein said controlled release core is an osmotic tablet.

20. (currently amended) The dosage form of claim 19 wherein the osmotic tablet consists ~~essentially~~ of:

(a) a core comprising ~~consisting essentially of~~:

(i) 50-98% of said metformin hydrochloride ~~or pharmaceutically acceptable salt thereof~~;

(ii) 0.1-40% of a binding agent;

(iii) 0-20% of an absorption enhancer; and

(iv) 0-5% of a lubricant;

(b) optionally a seal coat surrounding the core; and

(c) a sustained release membrane comprising:

(i) 50-99% of a polymer;

(ii) 0-40% of a flux enhancer and

(iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin hydrochloride ~~or pharmaceutically acceptable salt thereof~~.

21. (canceled).

22. (canceled).

23. (original) The dosage form of claim 1 wherein said core is substantially free from any gelling or expanding polymer.

24. (currently amended) The dosage form of claim 1 wherein said controlled release of said metformin hydrochloride ~~or pharmaceutically acceptable salt thereof provides a Tmax of 8-12 hours~~.

25. (original) The dosage form of claim 1 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.

26. (original) The dosage form of claim 25 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.

27. (canceled).

28. (canceled).

29. (canceled).

30. (canceled).

31. (canceled).

32. (canceled).

33. (canceled).

34. (canceled).